

### REMARKS

Claims 17 to 26, as amended, are pending. Applicant has amended claims 17 and 18 and added new claim 26. Attached hereto is a marked-up version of the changes made to the claims by the current amendment, which is captioned "Version with markings to show changes made." The amendments full support in the original specification and claims. Specifically, the amendment to claim 17 finds support, for example, at page 3, lines 12 to 13. New claim 26 finds support, for example, at page 2, lines 26 to 29. No new matter is presented. In view of the above amendments and following remarks, Applicant respectfully requests favorable reconsideration and a timely indication of allowance.

The Examiner rejected claims 17 and 19 to 25 under 35 U.S.C. § 112, first paragraph, as allegedly not enabled by the specification. Specifically, the Examiner contended that the specification, while enabling for a method encompassing administering *Belamcanda chinensis*, does not reasonably provide enablement for administration of an extract from any and all plants of the family Iridaceae. Applicant has amended independent claim 17, from which the other rejected claims depend, to recite that the extract is selected from the group consisting of *Belamcanda chinensis*, *Iris Germanica*, *Iris tectorum*, *Iris Illyrica*, and *Iris dichotoma* and/or comprises at least one of tectorigenin and tectorigenin glycoside. Applicant respectfully submits that amended claim 17 is fully enabled by the specification and respectfully requests that the rejection under section 112, first paragraph, be withdrawn.

The Examiner rejected claims 17 to 18 under 35 U.S.C. § 112, second paragraph, as allegedly indefinite based on the use of the term "extract". Applicant respectfully traverses this rejection. The Examiner states that because the extract itself is clearly essential to the invention, the steps by which the extract is obtained are also clearly essential and therefore must be recited in the claim language. Applicant respectfully disagrees. The present claims encompass all extracts that meet the other claim limitations, regardless of how they are extracted and regardless of the part of the plant from which the extract is obtained. One skilled in the art would be able to determine whether he or she is administering an extract in accordance with the present claims. Accordingly, Applicant respectfully requests that the rejection under section 112, second paragraph, be withdrawn.

The Examiner rejected claims 17, 18 and 24 under 35 U.S.C. § 102(a) as allegedly anticipated by Li (CN 1,159,340) or Ning (CN 1,158,261). Applicant respectfully traverses this rejection. Neither

Li nor Ning discloses producing an estrogen-type effect in a patient without causing a substantial uterotrophic effect, as presently claimed. The Examiner has not pointed to such a teaching in either of these references. In fact, one skilled in the art would expect the claimed extracts to exhibit a uterotrophic effect, which is undesirable in treating, for example, cardiovascular disease or osteoporosis. Accordingly, neither Li nor Ning anticipates the claimed method, and Applicant respectfully requests that the rejections over Li and Ning be withdrawn.

The Examiner rejected claims 17, 21 and 24 under 35 U.S.C. §102(b) as allegedly anticipated by Breton (WO 97/09056). Applicant respectfully traverses this rejection. Breton is directed to the use of in vitro cultured cells of Iridaceae and not extracts of naturally grown plants. Applicant has amended claim 17 to recite a medicament comprising an extract from an Iridaceae plant. The use of cellular extracts does not suggest the use of naturally grown Iridaceae plants because the ingredients of the cellular extracts depend on the culture conditions and thus are different from in vivo cultivation. In fact, Breton states, at page 1, lines 29 to 32, that the “pressure of selection imposed by the physico-chemical conditions due to the plant cell growth in vitro permits obtaining a standardized plant and round the year available plant material, in contrast to the plants obtained by in vivo cultures.” Thus, Breton actually teaches away from the use of the presently claimed extract. Accordingly, Applicant respectfully requests that the rejection over Breton be withdrawn.

The Examiner rejected claims 17 and 23 under 35 U.S.C. § 102(b) as allegedly anticipated by Soma et al. (U.S. Patent No. 5,382,430). Applicant respectfully traverses this rejection. The Examiner that Soma teaches the administration of a glycolipid extract from plants of the Iridaceae family. However, Soma does not teach or suggest the administration of an extract is selected from the group consisting of Belamcanda chinensis, Iris Germanica, Iris tectorum, Iris Illyrica, and Iris dichotoma, and/or an extract at least one of tectorigenin and tectorigenin glycoside, as recited in amended claim 17. Accordingly, Applicant respectfully submits that Soma does not anticipate the claimed subject matter and requests that the rejection under section 102(b) over Soma be withdrawn.

The Examiner rejected claims 17, 21 and 22 under 35 U.S.C. § 102(b) as allegedly anticipated by Bliadze et al. (SU 719,595). Applicant respectfully traverses this rejection. Bliadze discloses a tonic drink containing, *inter alia*, iris root. Bliadze also states that vitamin P reduces the brittleness of blood vessels, thus preventing arteriosclerosis. However, Bliadze does not teach or suggest that the vitamin P

is contained in an extract from an Iridaceae plant. In fact, Bliadze does not teach or suggest that any extract from an Iridaceae plant produces an estrogen-type effect in a patient without causing a substantial uterotrophic effect. Accordingly, Applicant respectfully submits that Bliadze does not teach or suggest the present invention and requests that the rejection under section 102(b) over Bliadze be withdrawn.

The Examiner rejected claims 17 and 24 under 35 U.S.C. § 102(b) as allegedly anticipated by JP 0738179A or Liu et al. (CN 1090498). Applicant respectfully traverses this rejection. JP 0738179A discloses a preparation for preventing skin aging. The Examiner states that “[a]s skin-aging is known in the art as a climacteric disorder, the reference anticipates the claimed subject matter.” (Office action at 11.) However, JP 0738179A nowhere teaches or suggests that the preparation produces an estrogen-type effect in a patient without causing a substantial uterotrophic effect, as claimed. Liu is directed to an oral contraceptive. Liu similarly does not teach or suggest that the contraceptive produces an estrogen-type effect in a patient without causing a substantial uterotrophic effect, as claimed. In fact, a contraceptive must necessarily have a uterotrophic effect, and thus Liu actually teaches away from the claimed invention. Accordingly, neither JP 0738179A nor Liu anticipates the claimed invention, and Applicant respectfully requests that the rejection under section 102(b) over these references be withdrawn.

The Examiner rejected claims 17 to 20 and 23 under 35 U.S.C. § 103(a) as allegedly unpatentable over Esaki and Petrie (U.S. Patent No. 6,008,208) in view of Shawl and Zhou et al. Applicant respectfully traverses this rejection. Esaki discusses the administration of tectorigenin to cause a weak estrogenlike action. Petrie teaches the administration of such compounds for treating osteoporosis. As acknowledged by the Examiner, neither Esaki nor Petrie teaches or suggests administering a medicament comprising an extract of Iridaceae, as claimed. Accordingly, the Examiner relies on Shawl and Zhou to teach that tectorigenin and tectorigenin glycoside could be obtained from a plant belonging to the family Iridaceae. The Examiner contends that it would be obvious to use the tectorigenin or tectorigenin glycoside obtained from a plant belonging to the family Iridaceae, as disclosed in Shawl or Zhou, in the methods of Esaki and Petrie. Applicant respectfully disagrees. The Examiner has pointed to no motivation to combine the references other than Applicant’s specification and hindsight. That it may have been obvious to try the extracted compositions disclosed in Shawl and Zhou in the methods of Esaki and Petrie is insufficient to establish a *prima facie* case of obviousness. “The mere fact that

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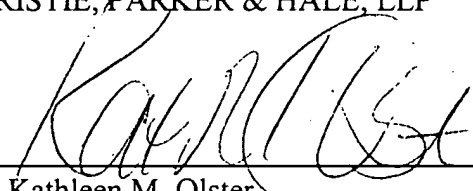
references can be combined or modified does not render the resultant combination obvious unless the prior art also suggests the desirability of the combination". M.P.E.P. § 2143.01 (emphasis in original). Accordingly, the combination of Esaki, Petrie, Shawl and Zhoe does not render obvious the presently claimed invention. Applicant therefore respectfully requests that the rejection under section 103(a) be withdrawn.

For all these reasons, Applicant respectfully submits that claims 17 to 26, as amended, are in condition for allowance, and a timely indication of allowance is respectfully requested. If there are any remaining issues that can be addressed by telephone, Applicant invites the Examiner to contact the undersigned at the number below.

Respectfully submitted,

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**VERSION WITH MARKINGS TO SHOW CHANGES MADE**

**In the Claims:**

Please amend claims 17 and 18 as follows:

17. (Amended) A method for producing an estrogen-type effect in a patient without causing a substantial uterotrophic effect, the method comprising administering to the patient an effective amount of a medicament comprising an extract from an Iridaceae plant, wherein the extract is selected from the group consisting of Belamcanda chinensis, Iris Germanica, Iris tectorum, Iris Illyrica, and Iris dichotoma, and/or comprises at least one of tectorigenin and tectorigenin glycoside, with the proviso that the medicament does not comprise Belamcandra [chinesis] chinensis extract [is not used] if the medicament is used for treating a peri-menopausal [and] or post-menopausal [disorders] disorder.

18. (Amended) A method according to claim 17, wherein the extract is a Belamcandra [chinesis] chinensis extract.